PHILIPS

K041949

JUL 3 0 2004

510(k) Summary

The following information is being submitted in accordance with the requirements of 21CFR 807.92.

Company Name:	Philips Medical Systems North America Company
Address:	22100 Bothell Everett Highway P.O.Box 3003 Bothell, WA 98041-3003, USA
Registration No.:	1217116
Contact Person: Telephone No.:	Lynn Harmer (425) 487-7312
Date Prepared:	July 12, 2004
Device (Trade) Name:	Allura Xper FD10
Classification Names:	Stationary X-ray system, 21CFR892.1680, Class II (code 90KPR) Angiographic X-ray system, 21CFR892.1600, Class II (code 90IZI)

Predicate Device:
The Allura Xper FD10 is substantially equivalent to the Integris Allura Flat Detector release 1.2, both manufactured by Philips Medical Systems Nederland B.V. The Philips Integris Allura Flat Detector release 1.2 received a 510(k) substantially equivalent determination in K031333 on May 13th, 2003.

Device description:
The Allura Xper FD10 is a stationary angiographic X-ray imaging system with a solid state x-ray imaging device for cardiovascular and vascular diagnostic and interventional procedures. The monoplane system can be configured as either a floor or a ceiling suspended G-arm frontal stand.

Intended use:
The Allura Xper FD10 is intended for use in cardiovascular and vascular x-ray imaging applications, including diagnostic, interventional procedures (such as PTCA and stent placement and atherectomies), pacemaker implantations and electrophysiology. It is compatible with specified magnetic navigation systems.

General Safety and Effectiveness information:
The device and its labeling will comply with the applicable requirements of:

- Title 21 Code of Federal Regulations, Subchapter J - Radiological Health, parts 1010, 1020.30, 1020.32 & 1040.10.
- Underwriters Laboratories standard for Safety UL60601-1 and be classified by Underwriters Laboratories (UL).
- ACR/NEMA DICOM digital imaging communication standard.

Conclusion:
The Allura Xper FD10 does not introduce any new indications for use, nor does the use of the device result in any new potential hazard. Philips Medical Systems Nederland B.V. considers the Allura Xper FD10 to be substantially equivalent with the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 0 2004

Ms. Lynn Harmer
Manager, Regulatory Submissions
Philips Medical Systems
North America Company
22100 Bothell Everett Highway
P.O. Box 3003
BOTHELL WA 98041-3003, USA

Re: K041949
Trade/Device Name: Allura Xper FD10
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: 90 IZI
Dated: July 16, 2004
Received: July 20, 2004

Dear Ms. Harmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: **Allura Xper FD10**

Indications for Use:

The Allura Xper FD10 is intended for cardiovascular and vascular x-ray imaging applications, including diagnostic, interventional procedures (such as PTCA, stent placement and atherectomies), pacemaker implantations and electrophysiology. It is compatible with specified magnetic navigation systems.

Prescription Use __yes_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __No___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K044949